8. PREMARKET NOTIFICATION 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR SURGICAL MASK

OCT 2 5 2005 K050689

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8.6 Date prepare: December,29, 2004

8.7 Trade name/proprietary name: Surgical Face Mask

8.8 Common name/usual name: Face Mask

8.9 Classification name: Mask, surgical

TRADE NAME	COMMON NAME	CLASSIFICATIOM NAME
Surgical Face Mask	Face Mask	Mask, surgical

8.10 Legally market device equivalence:

3M 1818 Tie-on Surgical Mask and 3M 1818FS Tie-on Surgical Mask with Face Shield
510k number: K940707
Manufacturer: 3 M

Crosstex ® Isolite®
Earloop Face Masks
K012602

8.11 Intended use:

Surgical Face Mask is a type of surgical mask covers the user's nose and mouth. And provides a physical barrier to fluids and particulate materials. The intended use is not only for surgical room but also for isolation, dental or medical procedure use. This products is intended for use in infection control practices to minimize contamination caused by

for surgical room but also for isolation, dental or medical procedure use. This products is intended for use in infection control practices to minimize contamination caused by exhaled and inhaled microorganisms, body fluids, and particulate material. In addition, the device is intended to reduce potential exposure of the wearer to blood and body fluids.

8.12 Indication for use (SEE APPENDIX IV)

surgical masks/Procedure Mask is a high 3 ply face mask is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patients and the operating room personnel from transfer of microorganisms, body fluids and particulate materials.

8.13 Device description

The Surgical Face Mask is a flat, pleated tie-on or elastic ear-loop mask consisting of 3-ply Non-Woven material; inner and outer cover web with middle different filter web sandwiched in between. It covers the nose and mouth of the wearer, and is held in place by tie string or elastic ear loop and a malleable plastic coated wire nose piece. For protection against airborne particles and splatters of blood and saliva...etc

According to Nelson report for the BFE (Bacteria Filtration Efficiency) up to 95% at 3.0 μm particle size.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2005

China Surgical Dressings Center Co., Ltd.
C/O Mr. Michael F. L. Chang
President
China Surgical Dressings Center Product
4 F. 232 JEN AI Rd., Sec. 4
Taipei, Taiwan
REPUBLIC OF CHINA

Re: K050689
Trade/Device Name: SURGICAL FACE MASK
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: October 17, 2005
Received: October 21, 2005

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): 050689

Device Name: Surgical Face Mask

Indications For Use:

Surgical masks/Procedure Mask is a high 3 ply face mask is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patients and the operating room personnel from transfer of microorganisms, body fluids and particulate materials.

Prescription Use _____ (Part21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_ V (21 CFE 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGEIF NEEDED)

Concurrence of CDRH , office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K050689